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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,184	04/14/2005	Brian Andrew Hills	13596-004US1	7882

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EXAMINER	
JAGOE, DONNA A	
ART UNIT	**PAPER NUMBER**
1614	

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10/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,184	HILLS ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/9/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are presented for examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 3-20 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 4-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to both a "process" of use and a "method". The claim embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only. *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990) *Id.* at 1551.

To advance prosecution in this case, the claims are being interpreted as method of use claims as per U.S. practice. This does not pardon the applicant from amending the claims to reflect U.S. practice.

Claim Rejections - 35 USC § 112

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-20 provide for the use of a SAPL in powder form, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

The term "improving efficiency" in claims 1 and 2 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a reasonable standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since no guidance is provided as to how "inefficient" a given value can be and still fall within the scope of the instantly claimed subject matter as circumscribed by the term "improved efficiency" the metes and bounds of the term are not clear, making it impossible to ascertain with reasonable precision when that term is infringed and when it is not.

The term "reducing deficiency" in claims 1 and 2 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a reasonable standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since no guidance is provided as to how

"deficient" a given value can be and still fall within the scope of the instantly claimed subject matter as circumscribed by the term "reducing deficiency" the metes and bounds of the term are not clear, making it impossible to ascertain with reasonable precision when that term is infringed and when it is not.

Regarding claim 1 that recites the terms SAPL (line 3 of the claim) and CAPD (line 5 of the claim), it is customary that the full name of the abbreviation be recited the first time the abbreviation is used in the claims. The meaning of every term used in a claim should be apparent from the prior art or from the specification and drawings at the time the application is filed. Applicants need not confine themselves to the terminology used in the prior art, but are required to make clear and precise the terms that are used to define the invention whereby the metes and bounds of the claimed invention can be ascertained. During patent examination, the pending claims must be given the broadest reasonable interpretation consistent with the specification. In re Morris, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997); In re Prater, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969).

Claim 7 recites the limitation "the use or method according to claim 6 in which the SAPL composition is a mixture of dipalmitoyl phosphatidyl choline (DPPC) or a phosphatidyl choline blend (PC) which is predominantly DPPC and phosphatidyl glycerol (PG). There is insufficient antecedent basis for this limitation in the claim because it depends from claim 6 wherein there is only a mixture of PC and PG recited. Amending the claim to depend from claim 1 would obviate this rejection.

Claim 17 recites the limitation "the use or method according to claim 15 in which the SAPL composition is a mixture of dipalmitoyl phosphatidyl choline (DPPC) or a phosphatidyl choline blend (PC) which is predominantly DPPC and phosphatidyl glycerol (PG). There is insufficient antecedent basis for this limitation in the claim because it depends from claim 15 wherein there is only a mixture of PC and PG recited. Amending the claim to depend from claim 2 would obviate this rejection.

Claim 18 recites the limitation "the use or method according to claim 16 in which the SAPL composition is a mixture of dipalmitoyl phosphatidyl choline (DPPC) or a phosphatidyl choline blend (PC) which is predominantly DPPC and phosphatidyl glycerol (PG). There is insufficient antecedent basis for this limitation in the claim because it depends from claim 16 wherein there is only a mixture of PC and PG recited. Amending the claim to depend from claim 3 would obviate this rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macnaught PTY LTD WO 91/12026 in view of Park et al. (Peritoneal Dialysis International 1989, Vol. 9, pages 75-78)

The claims are drawn to improving efficiency or reducing deficiency of ultrafiltration in continuous ambulatory peritoneal dialysis (CAPD) comprising administering at least one SAPL in powder form or dispersed or dissolved in a carrier (other than saline as in instant claim 3).

It is unclear how efficiency or deficiency is determined, so the examiner is basing the increased efficiency/reduced deficiency upon the increase of surface area as a result of a lack of adhesions. Park et al. teach that recurrent episodes of peritonitis that occur with CAPD with resulting fibrosis or adhesions might decrease effective peritoneal surface area and dialysis efficiency (page 75, column 1, paragraph 1).

Macnaught teaches that coating tissue surfaces with a phospholipids suspension or solution in a carrier such as propylene glycol reduces surgical adhesions (see abstract). Phospholipids, phosphoglycolipids, phosphodiol lipids

and phosphosphingolipids are disclosed (table 1, pages 4-5). The composition of DPPC with propylene glycol as a carrier is recited because of its poor solubility (page 5). Gels, pastes and viscous solutions are disclosed (see claim 5). Macnaught does not teach increasing efficiency of CAPD, however, Park et al. teach that surgical adhesions occur as a result of CAPD and reduce the surface area and decreases efficiency of dialysis. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the phospholipid compositions in a carrier such as propylene glycol to increase efficiency/reduce deficiency motivated by Macnaught who teaches the same phospholipids to reduce adhesions in the peritoneum and Park et al. that teaches that adhesions that result from CAPD decreases surface area of the peritoneum thereby reducing efficiency of the dialysis.

Regarding the specific combinations of DPPC and PG or PC and PG, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. "When there is only a finite number of pharmaceutically acceptable phospholipids/spreading agents to be tested for improved properties, it would have been obvious to one having ordinary skill in the art to employ different combinations of these agents.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

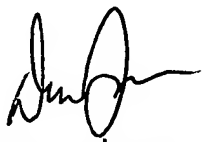
Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 9:00 A.M. - 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Donna Jagoe
Patent Examiner
Art Unit 1614

September 30, 2007